WC 07-257

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September 18, 2007

BY HAND DELIVERY

Federal Communications Commission
Attention: Julius Knapp, Chief
Office of Engineering and Technology
Washington, DC 20554

Re: Request for Waiver of Section 15.247(b)

Dear Mr. Knapp:

There is urgent public concern with patient safety in medical operating rooms, and specifically, with complications caused when surgical items used during surgery, such as disposable sponges, inadvertently are misplaced and left inside patients.[1] Such events can be followed by infection, disability, and even death.

Versoscan has developed a system that will improve patient safety significantly by electronically counting and tracking sponges and other surgical items that commonly enter and leave hospital or surgical center operating rooms during surgery. This system is depicted in the attachment and recently secured an exemption from approval from the Food and Drug Administration ("FDA"). Veroscan's OR-acle system uses RFID technology operating in the 902-928 MHz ISM band and, except for a wand when used briefly for detection including a body scan or around the patient, is compliant with the Commission's Rules. When used in high power

[1] This problem figured prominently in the news last month when Medicare announced that it would not pay hospitals the cost of treating conditions that result from an error such as this "that could reasonably have been prevented", and it is reported that private insurers are likely to make similar changes to their coverage. *See* August 19, 2007, New York Times, at: http://www.nytimes.com/2007/08/19/washington/19hospital.html?ex=1189051200&en=abcf73df3f32220f&ei=5070# (last visited on Aug. 31, 2007).

detect mode (also referred to as body-scan mode), the wand is only used for a short period (typically less than 2 minutes per measurement) during interim counts or as the operation is being completed to ensure that no tagged item remains in the patient. This aspect is critical to eliminating errors that threaten patient safety, but can be performed reliably only at a radiated power that exceeds the limits of FCC Rule 15.247(b).

We therefore request a waiver of the power limits codified in Section 15.247(b)[2] for the limited operation of the wand in the body-scan mode, subject to the safeguards and limitations described herein. As demonstrated below, grant of the requested waiver would serve the public interest, convenience and necessity by markedly improving the safety of patients undergoing surgery. The wand:

> (1) is automatically limited to a brief period (typically less than 2 minutes, but never exceeding 6 minutes) for any single measurement period;
>
> (2) is operable only within the confines of a fully-equipped hospital or surgical enter operating room; and
>
> (3) can be activated only by an authorized trained professional.

These aspects result in it being extremely unlikely that operation of this device would interfere with another device or service outside the control of the facility in which the operating room is located. We respectfully request prompt action on this request to permit this life-saving device to be used in hospitals as soon as possible.[3]

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[2] 47 C.F.R. § 15.247(b)(2006).

[3] *See* A. Rogers, E. Jones, D. Oleynikov, *Radio Frequency Identification (RFID) Applied to Surgical Sponges* (2007), attached.

AUTOMATED DETECTION SYSTEM CRITICALLY NEEDED IN OPERATING ROOMS FOR PATIENT SAFETY

There is estimated to be more than 10,000 instances in the United States each year when a foreign object accidentally is left inside a patient following conclusion of surgery. In an estimated 70-80 percent of such instances the item is a surgical sponge. Many such instances are followed by infection, disability, and even death. The cost to our healthcare system has been estimated to exceed $4 billion, and as noted above at footnote 1, Medicare and private insurers are moving to eliminate coverage for this type of operating room mistake. Eliminating this type of error now is a very high priority, and Veroscan can provide the solution as soon as its equipment is approved by the FCC.[4]

Currently sponges and surgical items used in operating rooms are manually counted upon entrance to and exit from the operating room, and counts are reconciled at the end of the surgery. The best manual procedures and counts, however, can be unreliable. Surgical staff changes during extended operations and unforeseen events occur that require attention to other aspects of the surgery, with the result that counts of sponges and other surgical items are temporarily suspended. Sponges can be lost or new sponges rushed into the room during surgery without being counted. The unfortunate result is that sometimes a sponge or another surgical item is left inside the patient with serious consequences.

While optical bar codes have been introduced to try to minimize the problem, they have proven to be insufficient. Bar codes require manual scanning and remain susceptible to miscounts and lost items due to human error. In addition, items with bar codes are not detectable when within a patient's body.

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[4] The FDA granted a Section 513(g) exemption from premarket notification [510(k)] on August 6, 2007, *see* attachment, which permits immediate marketing of this device.

Today procedures in hospital or surgical center operating rooms often call for the use of X-Rays to avoid inadvertently leaving an item inside a patient. X-Ray technology, however, has a less-than-desired success rate of only about 80 percent. In addition, as with all use of X-Rays, radiation exposure is of concern for the patient's safety and must be strictly limited. Non-ionizing radiation, such as that used by RFID tags, is a much safer alternative.

VEROSCAN'S SYSTEM INCREASES SAFETY AND LESSENS ERRORS

To increase patient safety, Veroscan has designed an automated system employing RFID technology for use in hospital and surgical center operating rooms. Our system will eliminate human counting errors and enable safer and more effective detection of sponges and surgical items in patients so that such items can be retrieved safely during the surgical procedure. The FDA recently issued a Section 513(g) exemption from premarket notification [510(k)], which permits its immediate marketing. All aspects of our system also comply with the applicable FCC rules, except the wand when used for a brief (but crucial) period of less than 6 minutes for any measurement when in body-scan mode, including interim counts or at the end of surgery to do a final check for any item inadvertently left in the patient or detection around the patient for any missing item.

Veroscan's system provides for automatic counting of sponges and surgical items in the hospital or surgical center operating room, and a body-scan during interim counts or at the end of surgery to ensure that no item is left in the patient. All functions operate within a complete interdependent system, such that the body-scan mode cannot be initiated unless the scanning wand is connected to the counting system and properly authenticated by a trained professional. While the attachment depicts the entire system, a waiver of Section 15.247(b) is needed only for the scanning wand, and only when it is used in body-scan mode for detection.

Veroscan's system is designed to increase patient safety by dramatically lessening opportunities for errors in hospital and surgical center operating rooms. The automated counting system, less prone to human error, virtually eliminates miscounts and dramatically reduces the time needed in the operating room to reconcile counts. Use of the wand for a body scan to ensure that no sponge or other surgical item is left in the patient is both safer for the patient and more reliable in detecting an item than today's X-Ray option.

WAND OPERATION IN BODY-SCAN MODE

Operation of Veroscan's wand is compliant with the FCC power limits in the normal mode used to count items. However, the power must be increased to reliably detect objects during a body scan. To ensure reliability in the critical body-scan mode, the wand must operate with a maximum peak transmit power (conducted) of 25 watts at 25% duty cycle (6.25 watts average power). Transmit time for this measurement typically is 2 minutes, and timers prevent the high power mode from being engaged for more than 6 minutes per measurement. The wand is constantly scanned downward over the area of interest when in body-scan mode, and the antenna provides no more than 8 dBi gain directed toward the body.

In addition, to ensure safety, scanning must be initiated manually and only by authorized personnel logged into the Veroscan system. Such personnel will be familiar with operation of the wand. The system requires multiple levels of permission in order for the wand to operate in the body-scan mode. When the body-scan mode is requested, all other scanning ceases and the base command unit is configured into a unique wand detect display and begins to log time and power, and initiates timers that will turn the mode off before 6 minutes is exceeded per measurement. In addition, visual and audible alerts are initiated on both the wand itself and an

accompanying interrogator unit to ensure that all personnel know that the wand is in its high power body-scan mode.

This system, with its safeguards, ensures that sponge and other surgical item counts are automatically accomplished and that reliable checks may be made of a surgical patient to ensure that no item is inadvertently left behind. Implementation of this technology and system will substantially increase patient safety and can significantly decrease healthcare costs.

CONCLUSION

Accordingly, Versoscan respectfully requests waiver of the power and antenna gain limits of Section 15.247(b) of the Commission's Rules. Grant of this request will contribute measurably to patient safety during surgery and can result in substantial savings in healthcare costs. The design and protections built into this system limit its use to no more than 6 minutes per measurement during a surgical procedure, and prevent its use in any location other than hospital or surgical center operating rooms where much higher-powered medical equipment authorized under the Commission's Part 18 rules also commonly is used. Timely grant of this waiver therefore will demonstrably serve the public interest, convenience and necessity.

Please direct any questions or concerns to Veroscan's outside counsel, David Siddall, at Paul, Hastings, Janofsky & Walker LLP, DavidSiddall@paulhastings.com, (202) 551-1802.

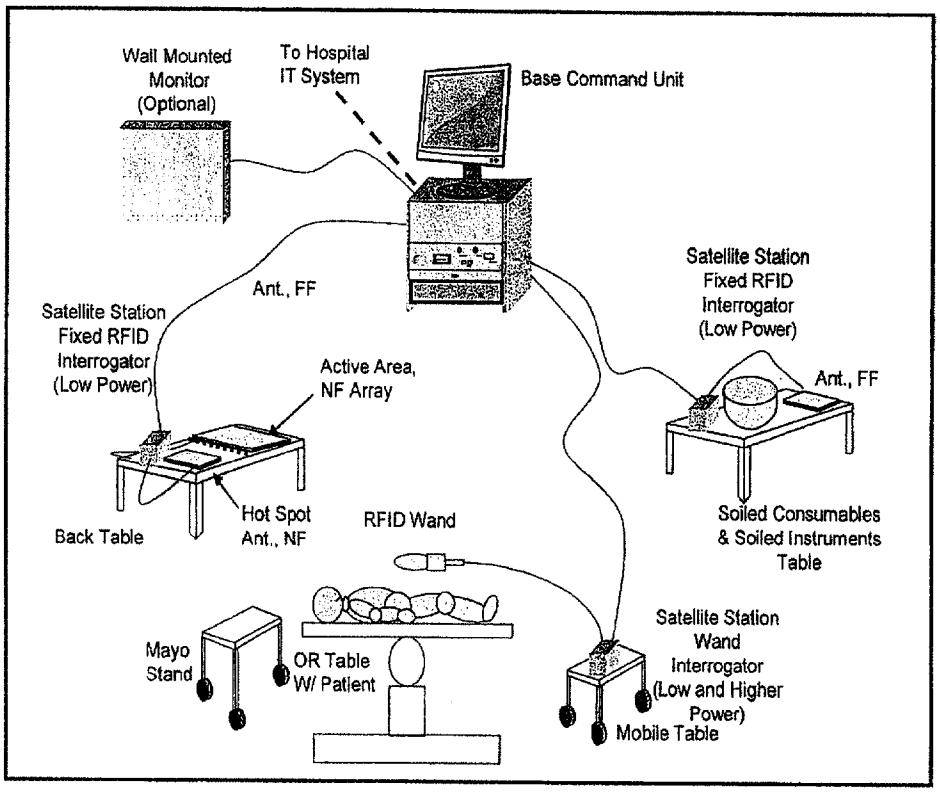
Sincerely,

John Volpi

John P. Volpi
Chief Technology Officer

VEROSCAN
NOTHING LEFT BEHIND

Veroscan Solution



- Fixed Interrogators
  - Low Power
- Wand Interrogator
  - Count Mode
    - Low Power
  - Detect Mode
    - Low Power
    - Higher Power

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Verosean Inc.
% Mr. Robert C. Hatch
President and CEO
5085 W. Park Boulevard
Plano, Texas 75093

AUG - 6 2007

Re: C070214
Device Name: Verosean OR-acle
Dated: June 29, 2007
Received: July 2, 2007

Dear Mr. Hatch:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Verosean OR-acle. Based on the information provided in your submission, we believe the Verosean OR-acle falls within Title 21 of the Code of Federal Regulations (CFR) 880.2740, Surgical sponge counter (Product Code – LWH). A surgical sponge counter is a Class I type device, exempt from the premarket notification [510(k)] requirements of the Act, subject to the limitations to the exemption found in 21 CFR 880.9.

Please be advised that our response to your 513(g) request for information does not mean that the Food and Drug Administration (FDA) has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 240-276-0132.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents my best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. My response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

If you have any questions regarding this letter, please contact Mr. Neil Ogden, Chief, General Surgery Devices Branch, at (240) 276-3600 or for general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph. D.
Deputy Director for Engineering
and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health

New Technology

Surg Endosc (2007)
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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Radio frequency identification (RFID) applied to surgical sponges

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Abstract
Use of gauze sponges that have been embedded with passive radio frequency identification (RFID) tags presents a high probability of reducing or eliminating instances of gossypiboma, or retained surgical sponge. The use of human counts during surgical operations, especially during instances where unexpected or emergency events occur, can result in errors where surgical instruments, most often gauze sponges, are retained within the patient's body, leading to complications at a later date. Implementation of an automatic inventory record system, for instance, RFID, may greatly reduce these incidences by removing the human factor and would improve patient safety by eliminating the current sponge count protocol. Experiments performed by placing RFID-labeled sponges within an animal and removing them have demonstrated that tags are at least partially readable inside the body cavity and fully readable once removed, suggesting the possibility of an automated sponge count system pending further development of this technology.

Key words: Laparotic sponge — Gossypiboma — RFID — Automated inventory

The importance of ensuring the removal of all foreign bodies from a patient after surgery can not be overstated. Retention of surgical instrumentation, most often surgical sponges, inside body tissues is an inconvenience for the patient at best and can lead to severe physiologic consequences in extreme cases. Most operating rooms use a count of sponges, sharps, and instruments to prevent this occurrence, but in the heat of surgery, especially when unforeseen circumstances occur during an operation that require emergency measures to be taken, mistakes can and do happen. These occasional mistakes in the sponge count, while rare, can result in both physical harm to the patient and damage to the surgeon via consequential malpractice suits. Furthermore, the sponge count protocol itself has been implicated as a hazard to patient safety [1].

The long-term objective of this research is the development of a radio frequency identification (RFID) system embedded within surgical sponges that will allow for a fast and accurate count during surgical operations. The overall objective of this system would be to eliminate errors in the sponge count by removing the human error factor and applying an automated, non-line-of-sight inventory system. RFID's power to inventory unique frequency signals for multiple items as well as the removal of the line-of-sight requirements of other technologies (i.e., barcodes) gives this technology the potential to meet the requirements of the surgical environment.

A recent study has estimated that as many as 1 in 1000-1500 surgeries worldwide may result in a retained surgical instrument [2]. When a retained surgical sponge is involved, the result is a generalized group of symptoms called gossypiboma, which includes development of abscess or granuloma around the sponge itself. A majority of hospitals use some form of sponge, sharps, and instrument count to prevent this, but no standardized method exists. In many cases the count procedure is defined by the individual hospital and is frequently omitted in cases of emergency or transvaginal surgery or for vaginal deliveries. Any number of factors can contribute to this possibility, including but not limited to surgical packs used during fascial closure, hurried counts at the end of long operations [3], emergency surgeries, or surgeries where complications arise over the course of the proceedings [2].

Typically, surgical sponges are embedded with radiopaque strips, allowing them to be visualized by postoperative X-ray. However, while this has reduced gossypiboma, it has not eliminated it. In one study 3 of 29 cases in which X-ray was used to screen for radiopaque sponges resulted in a false negative [4]. More

Correspondence to: E. Jones

importantly, these X-rays must be performed postoperatively, meaning that any sponges discovered must be removed via a second operation, exposing the patient to an even larger degree of risk for infection or trauma.

Accurate data regarding incidents of retained surgical instrumentation from surgery is difficult to discover. The Joint Commission for Accreditation for Healthcare Organizations (JCAHO) policy mentions that instances of "unintentionally retained foreign body without major permanent loss of function" do not require reporting. This leads to a gross underestimation of the incidents and incurred costs of retained surgical instruments, confounding efforts to compile numbers regarding them. Published popular press studies list worldwide surgical instrument retention rates ranging between 1 in 15,000 operations to as many as 1 in 100 operations. Of these, roughly two thirds consist of incidents of retained surgical sponges.

Presentation of gossypiboma is either acute or delayed, with acute symptoms resulting in abscess or granuloma and delayed symptoms resulting typically in adhesion formation and encapsulation, resulting in a subacute intestinal obstruction months or even years after the initial operation [3]. In some extreme cases, complications have been observed including perforation of the bowel, sepsis, and, in very rare instances, death [2].

RFID systems use individual transponders, typically referred to as tags, which emit a specific identification signal. Nearby antennae emit radio waves that are absorbed by the tag, converted to electrical energy, and then re-emitted at the tag's specific frequency [5]. These frequencies are then read by the antennae, creating an active inventory of each item read by the system [6, 7]. This inventory information is then usable by a variety of middleware applications, opening options for IMS, portal checkpoints, logistics, and access control systems.

An RFID sponge system would reduce gossypiboma by using a small handheld device to perform an automated count of inventoried sponges before, during, and after the operation, minimizing human error in surgical tool counts, and allowing for immediate discovery and retrieval of surgical sponges within the peritoneum.

A recent study performed by researchers at Stanford presented encouraging results for the application of RFID technology in surgical settings [8]. In a double-blind test involving RFID-embedded gauze sponges, surgeons were able to detect and remove sponges hidden within the abdominal cavity using a simple handheld device. Both the wand and sponge were created by ClearCount Medical Solutions (Pittsburgh, PA).

Materials and methods

The first objective of our study, testing the current RFID technology's ability to function within the requirements of an operating room setting, consisted of a series of experiments involving submersion of RFID tags in body fluids (primarily water). Tags were affixed with standard adhesive to the consumer-bought gauze sponges and submerged in water to test for tag readability when wet. Once that information had been obtained, the next objective was to design a prototype "smart sponge." Issues that needed to be addressed during this step included identifying the existing RFID tag/reader combination which resulted in the desired accuracy and determining optimum placement of the RFID tags on the sponge surface for optimum readability and resistance to mechanical stress. Assembly of this prototype was tested by placing the RFID-labeled surgical sponges within the abdominal cavity of a euthanized pig cadaver and then retesting readability upon removal.

Once all of these objectives are met, the entire system will be assembled for final experimental confirmation of function and fine-tuning via implementation in a simulated or actual operating theatre.

Results

The initial experiment indicated that water would prove to be the primary obstacle to overcome for project success. While the porcine test resulted in positive read rates when the sponge was placed inside the body cavity and removed, full submersion or the sponge into water caused much more disruption in reads. Specifically, the read range seemed to be reduced sharply from an average of 18 20 in. between the reader and sponge to 4-6 in. as a result of full submersion and removal, along with a slight decrease in overall tag readability.

Experiments comparing performance with labels on the exterior of the sponge versus embedded showed a much better performance for tags on the outside of the sponge, presumably as a result of the removal of the intervening layer of liquid between reader and sponge. Additional testing demonstrated a positive correlation between this relationship. Initial concern arose from the possibility of separation of the RFID tag from the sponge, but further testing has shown this to be unlikely. Any weakening of the adhesive can be compensated for in later prototypes through use of water-resistant adhesives and/or through printing the RFID antenna directly onto the sponge itself.

Release of second-generation RFID technology (Gen 2) during the testing phase of our study opened the possibility for utilization of more rugged RFID transponders in the smart sponge system. Gen 2 technology features better range along with a more consistent read rate and resistance to various factors that hinder RFID read accuracy (such as water). In actual practice, this translated into a greatly increased read accuracy, even with the tag placed inside of the sponge.

One initial goal of the project was to allow readability of the RFID tags through a patient's skin, thus allowing mobile RFID readers to be used to locate missing sponges within a patient's body cavity. No Generation 1 RFID tags that were tested were capable of fulfilling this criterion. However, upon repeating the experiment with Gen 2 technology, tags were read effectively and accurately while in the pig's body cavity through the intervening layer of skin. Additional testing will be required to determine an accurate failure rate for these devices, but initial results suggested that, in many cases, this failure rate may be extremely low.

X-rays taken of sponges embedded with RFID tags were clearly visible because of the highly metallic content of the antenna inks. Thus, if an RFID tag is damaged or otherwise rendered unreadable, they should be

able to perform the same task as the radiopaque-labeled sponges until such time as RFID technology improves to allow for 100% reliable location within the patient's body cavity.

Discussion

Early experimental results strongly suggest that current RFID technology can be used to inventory surgical sponges accurately during an operation and with minimal human error. Specifically, Gen 2 Alien Squiggle T Tags (Morgan Hill, CA) have repeatedly demonstrated a 99% read accuracy when wet, even when submerged within water for up to an hour. In addition, these tags demonstrated the ability to be read with a reliable level of accuracy through the skin of a patient, even while wet from blood.

Given these data, an RFID sponge inventory system can be envisioned wherein each sponge is read entering the OR, as it is being placed within the patient, and finally at the end of the operation itself. A list of each sponge's ID number from the beginning of the operation and at the end could be compared, with any discrepancies visible immediately. If a sponge is missing, the patient's body can then be scanned with the same handheld RFID reader to locate the approximate location of the tag within the patient's body. If for some reason the tag can not be located, the metallic ink used for printing the RFID antenna will allow for tag identification via X-ray, much like the currently used radiopaque strips. With a high enough level of sophistication, this system can be fine tuned to a level of accuracy where the human sponge count will not be necessary, as the automated inventory system will be more accurate and free of human bias. This will result in an overall increase in efficiency for the operating room and an increase in patient safety.

The immediate reduction in gossypiboma cases would result in an increase in patient safety and efficiency in the OR and a reduction in malpractice suits for the medical community at large. Any sponges that are left within a patient would be identified immediately, allowing retrieval before the surgeon closes up, thus eliminating the need to perform a second operation to retrieve the sponge. Moreover, there would be a direct benefit for the surgeon because the operating room would be more efficient because of the elimination of lengthy counts and recounts at the end of each operation. A reduction in the number of miscounts would also reduce the need to X-ray the site of the operation to locate the sponge, decreasing the amount of time spent on this tedious task and minimizing the patient's radiation exposure.

An RFID reader such as the MC-9000G (Symbol Technologies, now part of Motorola), which was used for this study, typically costs $5000. Estimates indicate that the cost to place an RFID tag onto a surgical sponge during the manufacturing process would be negligible. As such, the $5000 price tag should be representative of the cost of a basic RFID system for sponge identification in the operating room. When compared to the 2 million dollars in indemnities paid to patients with retained surgical sponges during a seven-year period [4], the financial benefits for hospitals become clear.

Once the necessary technology is developed and further testing completed, the smart sponge system should be capable of fulfilling this requirement. In addition, a similar methodology can be used to radiolabel other surgical instruments. With all of the surgical tools in an operating room tagged by RFID, it will require only a small step on the part of hospital organizers to branch into an RFID-managed inventory control system, smart shelf technology, real-time location systems, and numerous other applications.

References

1. Christian CK, Gustafson ML, Roth EM, Sheridan TB, Gandhi TK, Dwyer K, Zinner MJ, Dierks MM (2006) A prospective study of patient safety in the operating room. Surgery 139: 159–173
2. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ (2003) Risk factors for retained instruments and sponges after surgery. N Engl J Med 348: 229–235
3. Zbar AP, Agrawal A, Saeed IT, Utidjian MR (1998) Gossypiboma revisited: a case report and review of the literature. J R Coll Surg Edinb 43: 417–418
4. Kaiser CW, Friedman S, Spurling KP, Slowick T, Kaiser HA (1996) The retained surgical sponge. Ann Surg 224: 79–84
5. Clampitt HG, Jones EC (eds) (2006) RFID Certification Textbook. PWD Group Inc., Houston, TX
6. Bhuptani M, Moradpour S (2005) RFID Field Guide: Deploying Radio Frequency Identification Systems Sun Microsystems, Santa Clara, CA,
7. Shepard S (2005) RFID: Radio Frequency Identification. McGraw-Hill, New York
8. Macario A, Morris D, Morris S (2006) Initial clinical evaluation of a handheld device for detecting retained surgical gauze sponges using radiofrequency identification technology. Arch Surg 141: 659–662